

Summary of Safety and Effectiveness
TMJ Implants, Inc. Total Temporomandibular Joint Replacement System

I. GENERAL INFORMATION

Device Generic Names: Metal-on-Metal Total Joint Replacement System

Device Trade Names: TMJ Fossa-Eminence/ Condylar Prosthesis System
Components are called:

- 1) TMJ Fossa-Eminence Prosthesis System
- 2) TMJ Patient Specific™ Fossa-Eminence Prosthesis System
- 3) TMJ Universal Arthro-Chrome™ Condylar Prosthesis System
- 4) TMJ Patient Specific™ Arthro-Chrome™ Condylar Prosthesis System
- 5) TMJ Christensen-Chase Arthro-Chrome™ Condylar Prosthesis System

Applicant's Name and Address: TMJ Implants, Inc.
17301 W. Colfax Avenue, Suite 135
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Premarket Approval (PMA)
Number: P000023

Date of Panel
Recommendation: May 11, 1999

Date of Notice of Approval to
the Applicant: January 5, 2001

II. DEVICE DESCRIPTIONS

TMJ Fossa-Eminence Prosthesis

The TMJ Fossa-Eminence Prosthesis is designed to provide a thin, rigid, well-fitting prosthetic covering for the articulating surface of the temporomandibular joint comprised of the glenoid fossa and the articular eminence of the temporal bone. The articular surface of the prosthetic glenoid fossa and articular eminence is highly polished to minimize friction in joint movement.

The prosthesis, and the screws with which it is to be secured to the skull, are manufactured from surgical Co-Cr-Mo alloy (ASTM F75 / ASTM F799). These devices are intended for permanent implant and are for single use only.

All components of the Fossa kit, including individual prosthesis, drills and screws are sterilized by gamma-irradiation or e-beam radiation (2.5 Mrads), and are packaged in individual double-peel PETG and Tyvek containers.

Two additional NON-STERILE Fossa kits accompany this TMJ Fossa-Eminence Prosthesis System and are essential for its use. The Fossa-Eminence Trial Sizing System contains trial sizer components for each size of implant. The Instrument Kit contains screwdrivers and Fossa-Eminence holders.

These two accompanying kits must be steam sterilized prior to use in accordance with procedures outlined in Sections 8 and 9 of the Instructions for use.

The TMJ Condylar Prosthesis

The TMJ Condylar Prosthesis, intended to be used with the Fossa-Eminence for total joint replacement, is designed to replace the articular surface of the mandibular condyle.

The TMJ Condylar Prostheses systems are designed to seat against the TMJ Fossa-Eminence Prosthesis and to be secured to the ramus of the mandible with cobalt chrome alloy screws. The Universal prosthesis is manufactured in three lengths, and is designed to be used on either the right or left side. The Christensen/Chase Condylar Prosthesis is also available in three lengths and is manufactured specifically for either the right or left side.

The entire Arthro-Chrome™ prosthesis and the screws with which they are to be secured to the ramus, are manufactured from surgical Co-Cr-Mo alloy (ASTM F75/ASTM F799). These devices are intended for permanent implant and are for single use only.

All components in this Condylar Prosthesis kit, including individual prosthesis, drills and screws are sterilized by gamma-irradiation or e-beam radiation (2.5 Mrads), and are packaged in individual double-peel PETG and Tyvek containers.

Two additional kits accompany this TMJ Condylar Prosthesis System and are essential for its use. The Condylar Trial Sizing System contains sterile disposable trial sizer components for each size of implant, as well as a sizing template. The NON-STERILE Instrument Kit contains screwdrivers and holders.

The accompanying instrument kit must be steam sterilized prior to use in accordance with procedures outlined in Sections 8 and 9 of the Instructions for use.

II. INDICATIONS FOR USE

The TMJ Metal-on-Metal Total Joint Replacement Prostheses System is indicated for reconstruction of the temporomandibular joint. Patients should be considered if they have one or more of the following conditions:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment;
- Recurrent fibrous and or bony ankylosis not responsive to other modalities of treatment;
- Failed tissue graft;
- Failed alloplastic joint reconstruction; or
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality or pathologic lesion.

CONTRAINDICATIONS

The TMJ Metal-on-Metal Total Joint Replacement System should not be used for patients with one or more of the following conditions:

- Infection or malignancy in the head or neck region
- Known allergy to any of the components of the system
- Ability to exert significant post-operative masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and fracture of the device or loosening of the screws

III. WARNINGS

- **Dynamic fatigue tests were conducted on the TMJ Implants Metal-on-Metal Total Joint Replacement System with a force applied vertically to the device. No failures occurred at 130 lbs. Physicians should carefully consider the results of these fatigue tests when patients present with particular anatomical considerations or unusual masticatory forces.**
- **PERFECT THE TECHNIQUE FOR IMPLANTATION**
It is strongly recommended that the surgeon perfect the technique for implantation of this prosthesis through attendance at surgical demonstration courses, use of instructional video, and manipulation of replica models. Instructional videos and literature are available from TMJ Implants, Inc. TMJ Implants, Inc. can provide names of individuals, with extensive experience, independent from the company, for consultation prior to surgery.
- **READ ALL ACCOMPANYING LABELING**
Prior to use, the surgeon must read the entire Instructions For Use and device labeling.
- **TEST FOR ANY SUSPECTED SENSITIVITY TO MATERIALS.**
If the patient's history suggests allergy to costume jewelry or other metals, such as Nickel, the patient should undergo appropriate testing for sensitivity to Co-Cr-Mo

alloy. Upon request, TMJ Implants, Inc. will supply a sample of this alloy and/or the chemical composition for pre-operative allergy testing. Should patch testing be positive then some alternate surgical plan should be considered.

- **IF LONGER SCREWS ARE NECESSARY:**

Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge any auditory structure, middle cranial fossa, or any neuro/vascular structures.

- **IF EXCISING BONE:**

When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

IV. PRECAUTIONS

Prior to Surgery

- Special attention should be paid to patient selection. Careful evaluation should be made of patients with disorders that might interfere with their ability to comply with the limitations and precautions necessary to achieve beneficial outcome from this implant.
- All TMJ Metal-on-Metal Total Joint Replacement Prostheses, screws, drills, and the Condyle sizers are provided sterile. Inspect sealed sterile package before opening. If seal is broken, do not use. Do not resterilize.
- Prior to use, the Instrument Kit containing screwdrivers and Fossa-Eminence holders must be sterilized as outlined in Sections 8 and 9 of the device labeling.
- The surface of the device must remain clean and free of debris prior to implantation.
- The implant must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.
- The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage may cause weakening or fatigue of the metal or fracture of the part.

During Surgery

- The TMJ Prosthesis System must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. The screws and drills used with the TMJ Prosthesis System have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Implants, Inc. in the TMJ Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.
- It is strongly recommended that at least four (4) Fossa-Eminence screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence Prosthesis.
- It is strongly recommended that at least six (6) condylar screws for the Universal Condylar Prosthesis and nine (9) condylar screws with the Christensen-Chase Condylar Prosthesis be used, where practical, to achieve firm fixation of the TMJ Condylar Prosthesis. Care must be taken to secure at least 3 screws in the topmost holes, where practical.
- It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The Condylar Prosthesis articulating surface should preferably be centered in the Fossa and should not contact the screws of the Fossa-Eminence Prosthesis.

V. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Types of adverse events observed in the clinical use of the TMJ Implants, Inc. Metal-on-Metal Total Joint Replacement System include:

- Postoperative pain, swelling, jaw muscle spasm
- Facial nerve and muscle weakness or paralysis
- Dislocation of the joint
- Infection
- Degenerative joint changes and development of adhesions
- Nausea and vomiting
- Perioperative bleeding
- Seizures
- Malocclusion

In addition to the adverse events identified above, potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to:

- Hematoma formation
- Hemorrhage
- Dental malocclusion, jaw dysfunction, limited range of motion
- Foreign body or allergic reactions to the device materials

- Rejection of the device
- Wear, displacement of the device or implant loosening
- Fracture of the device
- Hearing problems
- Surgical damage to anatomical structures adjacent to the TMJ
- Patient discomfort
- Speech problems
- Facial deformity

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures may include reconstruction of the temporomandibular joint using autogenous or allogenic tissue grafts of bone, soft tissue, or cartilage or using another viable alloplastic implant.

VII. MARKETING HISTORY

The devices were previously on the market as Preamendments Class III devices. The applicant submitted their initial PMA application in response to the final rule published in the Federal Register of December 30, 1998, requiring the submission of PMA applications for temporomandibular joint prostheses by March 30, 1999.

VIII. SUMMARY OF PRECLINICAL STUDIES

Biocompatibility

Tests were conducted to assess the cobalt chrome used in these devices. The tests conducted included: in-vitro Cytotoxicity, Genotoxicity, Mutagenicity, Irritation/Intracutaneous reactivity, Systemic Toxicity, and Contact Sensitization. All test results demonstrated the biocompatibility of the implant material. Results of a literature search also supports the suitability of this material for the chosen application.

A one-year assessment of the effects of wear particulates of cobalt-chrome on the temporomandibular joint space of 12 New Zealand white rabbits was conducted. This study indicated that after an early mild to moderate reaction to the particles, the joint spaces showed no lasting inflammatory response. No foreign body reaction was seen, and no giant cells were noted at any time. All other organ pathologies were normal, as were the results of all blood studies.

Material Characterization

Material Characterization confirmed the chemical composition and material properties of the implant materials. Potentiodynamic testing conducted on the cobalt-chrome alloys confirmed the low corrosion potential of these materials. Dimethylglyoxime testing determined the amount of nickel released from the cobalt-chrome alloy was below the detectable limits of the test. Even with undetected nickel release, nickel sensitive patients should continue to be warned about the presence of nickel in this device.

Modeling

Both Finite Element Analyses and Kinematic modeling of the implant components were conducted to determine the effects of stress and movement on the performance of the devices. These Finite Element and Kinematic models confirmed that the stock devices were mechanically a worse case scenario as compared to the patient specific devices. Therefore the stock devices were used for all mechanical testing procedures.

Mechanical Testing

Mechanical testing relating to the performance of the devices included Fatigue, Wear, Static Load, and Contact Stress Analysis. These mechanical tests were performed on total joint prosthesis configurations, using a stock TMJ Condylar Prosthesis with a Fossa-Eminence prosthesis.

Fatigue

Fatigue tests were performed on 14 metal-on-metal combinations for 10 million cycles or to failure, but the tests were done at three different times under 2 protocols. Loads ranged from 130 lbs to 336 lbs. Five (5) samples achieved run-out condition (10 million cycles). All 14 points were plotted along a load/number of cycles curve. A statistical justification was provided to justify pooling the different test groups together on one curve. The fatigue limit is estimated to be 130lbs.

Wear

Wear testing was conducted for 2 million cycles at a rate of 2 Hz, in bovine serum at 37 °C. A cyclic load pattern varying from 10 to 35 lb was applied to the components, while a 30° arc of motion was applied by the condylar head over the fossa component. Wear patterns in the in-vitro test samples showed single wear zones with parallel surface scratches oriented in a uni-axial direction of motion. Surface profiling, both before and after the wear testing, indicated the average wear of the metal-on-metal TMJ implants was 0.197 mm³ per million cycles. Mass measurements showed an increase in mass after testing so the mass measurements were set aside as being erroneous.

The wear test results were compared with the results of an analysis of explanted devices. The in-vivo results showed evidence of randomly oriented scratches, indicating multi-axial motion. Also, the contact surfaces of the retrieved explanted devices were significantly smaller and were characterized as smoother and more polished than the in-vitro wear test samples. The in-vivo results are probably a better indicator of wear patterns.

Static Load

Static load tests indicated that the maximum loads the devices will withstand are greater than those seen in-vivo. The metal-on-metal devices were subjected to forces of at least 448 lb before failure. Failure was defined as implant fracture, extensive bending, or component dislodgment from the mounting.

Static bend tests were also conducted to determine the effect of etching on the bend strength of the components. After etching the components had a yield strength of 109 lbs. and maximum load at failure of 217 lbs. This result indicates that etching reduces maximum load before failure, however this should not effect the devices use clinically.

Contact Stress Analysis

Contact area was measured and contact stress was analyzed for the metal-on-metal components. Contact areas ranged from 1.62 to 4.84 mm² for the metal-on-metal configuration. As expected, for increased loads, the contact areas also increased. The average contact pressure, assuming a uniform pressure distribution, ranged from 2592 psi to 7011 psi for the metal-on-metal configuration. All stress measurements were below the yield strength for ASTM F 75-98 Cobalt-Chrome alloy (65,000 psi).

Finished Product Analysis

Casting and Finishing, and Mating Tolerance analyses were performed. The Casting and Finishing report characterized the effect of the manufacturing process on the microstructure of the cast CoCr components. Random scratches and surface features were noted, believed due to the hand-polished nature of these devices. The etched metal surfaces revealed a dendritic microstructure. This microstructure is common for metallic materials. It is unclear what influence, if any, the microstructure has on the failure mode.

The mating tolerance analysis was conducted to determine the contact interference between the fossa and condylar TMJ components. The results indicate that the vertical distance between the fossa surface and the condylar head increases with increasing distance from the point of contact. The total angle of freedom in the mating tolerance is 70 degrees. Since this system is designed for point contact, its mating tolerance is appropriately large compared to other total joint systems.

Sterilization

Sterilization validation and bioburden studies confirm that the materials can withstand the sterilization process and sterility assurance levels of 10⁻⁶ are achieved. Sterilization validation was conducted per AAMI/ISO 11137, Method 1. Quarterly bioburden studies and dose audits are conducted to confirm the continuing validity of the sterilization process. The packaging materials used for the implantable products are PETG medical grade blister stock and DuPont Tyvek medical grade lidding stock.

IX. SUMMARY OF CLINICAL STUDIES

There have been two studies conducted that support the safety and effectiveness of the TMJ Metal-on-Metal Total Joint Replacement Prostheses System. The first is the TMJ Implants, Inc. Registry; the second a prospective clinical study, TMJ-96-001.

The Registry is a collection of data on patients that receive a TMJ Implants device. The primary purpose of the Registry is for device tracking. Monitoring clinical progress is a secondary function. The operating surgeon is asked to voluntarily submit baseline assessments of pain and interincisal opening and then asked to submit clinical reports at 6 months, 1 year, 18 months, 2 years and yearly thereafter.

The prospective study, TMJ-96-001 was designed to evaluate the ability of the TMJ Condylar Prostheses used in conjunction with a TMJ Fossa-Eminence Prostheses (total joint replacement) to significantly reduce TMJ pain and improve interincisal opening in appropriately selected patients. An additional objective of the prospective study included a review of device related adverse events occurring during the study.

Pain measurements for both studies were recorded using a 10cm Visual Analog Scale (VAS). The left side of the scale represented no pain while the right side represented the most severe pain imaginable. The patients' were instructed to mark a vertical line on the scale to indicate their perceived level of pain. At the point where this vertical line crossed the horizontal scale, a measure was recorded using a ruler graduated in millimeters. Interincisal opening was measured in millimeters using a Therabite™ Scale. The interincisal opening was measured at the point at which the patient cannot open his/her mouth any wider.

A. TMJ Implants, Inc. Registry

Demographics

The Registry data was described in two ways:

1. cross-sectional data, where serial data on patients were not available, and
2. cohort data, where serial data on patients were available

There were 425 total joint recipients representing 1309 devices included in the cross-section data set. The mean age of the cross-section group of patients was 42 ± 12 years. The cross-sectional data patients were 89% female.

There were 63 patients representing 204 devices in the cohort data set. The majority of the patients received "stock" devices. The mean age of patients was 41 ± 12 years for the cohort. The cohort data patients were 91% female. No difference between age and gender among the cross-section group and cohort was demonstrated, $p > 0.05$.

Pain and Diet Restriction: Total Joint Reconstruction

From the Cross-section data set, there is a reduction in pain and diet restriction within the first month after surgery, as demonstrated by Figure 1. Patients appear to have their lowest pain level within 12 months of surgery and maintain that level of improvement or slightly above through 4 years implant duration. A similar trend of pain reduction is demonstrated with a cohort of 63 patients with complete data through 2 years implant duration, Table 2. Approximately one-third of the cohort has complete data at 3 years. These data are not included in the analysis. By applying a test of contrasts to the 2-year cohort, a significant reduction in pain at every time period is demonstrated when compared to the pre-op value, $p < 0.0001$. Additionally, an ANOVA F-Test was applied to the cohort. The overall test is significant at $p < 0.0001$.

Figure 1: Total Joint, Reduction in Pain and Diet Restriction

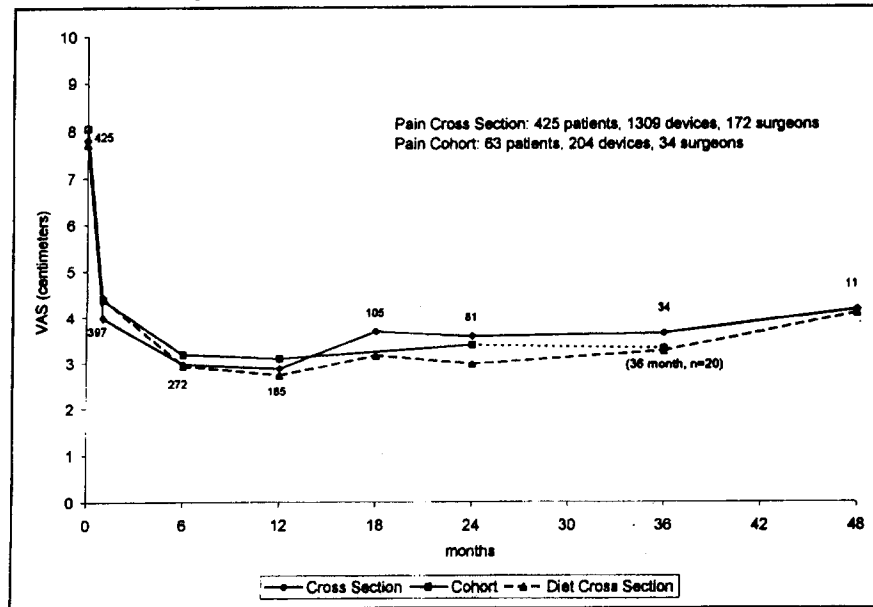


Table 1: Total Joint, Pain and Diet Cross Section Data

	Pain							
Months	0	1	6	12	18	24	36	48
Mean	7.8	3.9	3.0	2.9	3.7	3.6	3.7	4.2
N	425	397	272	185	105	81	34	11
	Diet							
Months	0	1	6	12	18	24	36	48
Mean	7.7	4.4	2.9	2.7	3.2	3.0	3.3	4.1
N	386	363	258	180	105	78	34	11

Table 2: Total Joint, Pain Cohort Data

Pain					
0	1	6	12	24	36
8.0	4.4	3.2	3.1	3.4	3.7
63	63	63	63	63	20

Interincisal Opening: Total Joint Reconstruction

From the Cross-section data set, there is improvement in the interincisal opening at 6 months after surgery, as demonstrated by Figure 2. Patients appear to reach their greatest improvement at 12 months after surgery and maintain that level of improvement through 3 years implant duration. A similar trend of improvement in opening is demonstrated with a cohort of 57 patients with complete data through 2 years implant duration, Table 4. Approximately one-third of the cohort has complete data at 3 years. By applying a Test of Contrasts to the 2-year cohort, a significant improvement in opening is demonstrated at

every time period when compared to the pre-op value, $p < 0.0001$. Additionally, an ANOVA F-Test was applied to the cohort. The overall test is significant at $p < 0.0001$.

Figure 2: Total Joint, Improvement in Opening

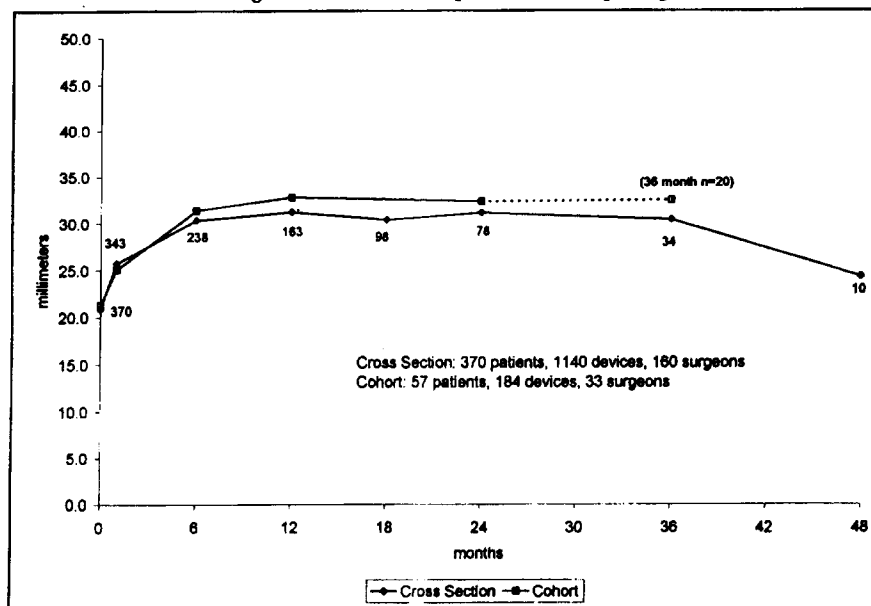


Table 3: Total Joint, Opening Cross-Section Data

Opening								
Months	0	1	6	12	18	24	36	48
Mean	20.9	25.8	30.4	31.2	30.4	31.1	30.4	24.3
N	370	343	238	163	98	78	34	10

Table 4: Total Joint, Opening Cohort Data

Opening					
Months	0	1	6	12	24
Mean	21.2	25.1	31.4	32.8	32.4
N	57	57	57	57	57

B. Prospective Study – TMJ-96-001

Demographic data were available from 43 subjects implanted with a TMJ Metal-on-Metal Total Joint System. The mean age of this population was 44 ± 13 years with a range of 24 to 74 years. The majority, 40 (93%), were female and Caucasian, 37 (86%). There were two (2) African-Americans and two (2) Hispanics, and one (1) Native-American. The most frequently reported indications for total joint replacement were previously failed implant surgery, 31%; recurrent fibrous or bony ankylosis, 29%; degenerative joint disease, 13%; and trauma, 9%. The remaining 18% included resorptive joint pathology, inflammatory arthritis, internal derangement, and unreported.

Reduction in Pain and Diet Restriction: Total Joint Reconstruction

On average, for patients with total joint replacements, there was a 64% reduction in pain and diet restriction by the 6-month post-op visit to 2.9 and 2.7 cm, respectively, as shown in Figure 3. Between 12 and 18 months, however, the mean pain and diet scores increased to above 3cm and then returned to near the 6-month level by 24 months. A comparison of the historical data from patients with pain scores > 3.0 cm at 12 months and those with pain scores of ≤ 3.0 cm at 12 months indicate that all 10 patients presenting with pain scores > 3.0 cm at 12 months were all multiply operated patients and 7 of the 9

patients presenting with pain scores ≤ 3.0 cm at 12 months were multiply operated. However, of the former group (>3 cm), besides being multiply operated, 6 of the 10 also had previously failed implant surgery, whereas of the latter group (≤ 3.0 cm), only 1 of the 7 patients that are multiply operated had experienced failed implant surgery. All other confounding variables associated with the patients histories such as trauma, degenerative disease, ankylosis, osteochondritis dessicans or avascular necrosis, are of similar frequency among both groups. Therefore, it appears that those patients who experienced previously failed implant surgery had a less stable post-op course than those patients who did not. A similar anomaly in the data at 18 months is also seen with the registry data for total joint replacement, but not as marked, Figure 4. The sample size for this time period in the registry cross-section data is 105. Therefore, sample size at this time period may be a factor in the variability of the data as presented below. These results are interim results and final conclusions cannot be drawn until all patients have completed at least 3 years and the data collected and analyzed.

Figure 3: Reduction in Pain, Total Joint Replacement

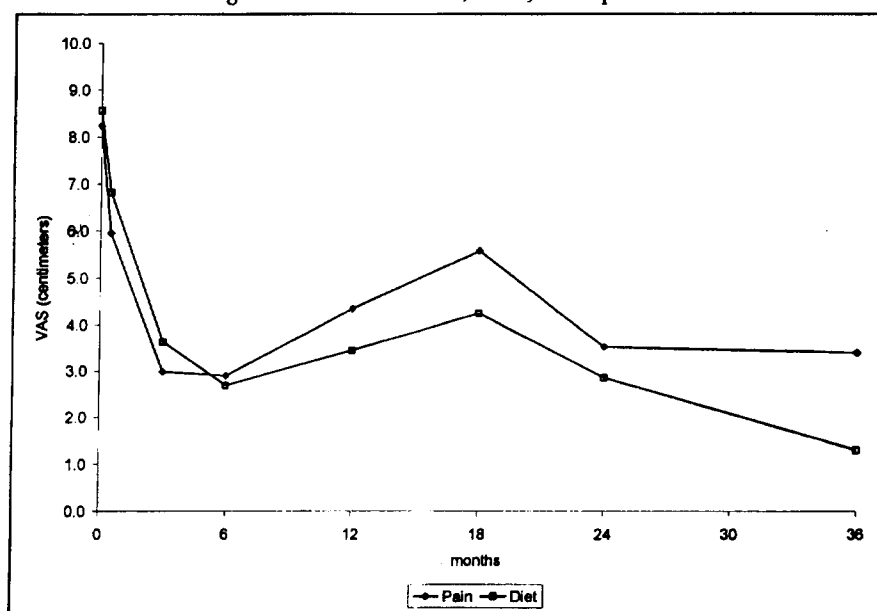


Table 5: Mean values, Reduction in Pain, Total Joint

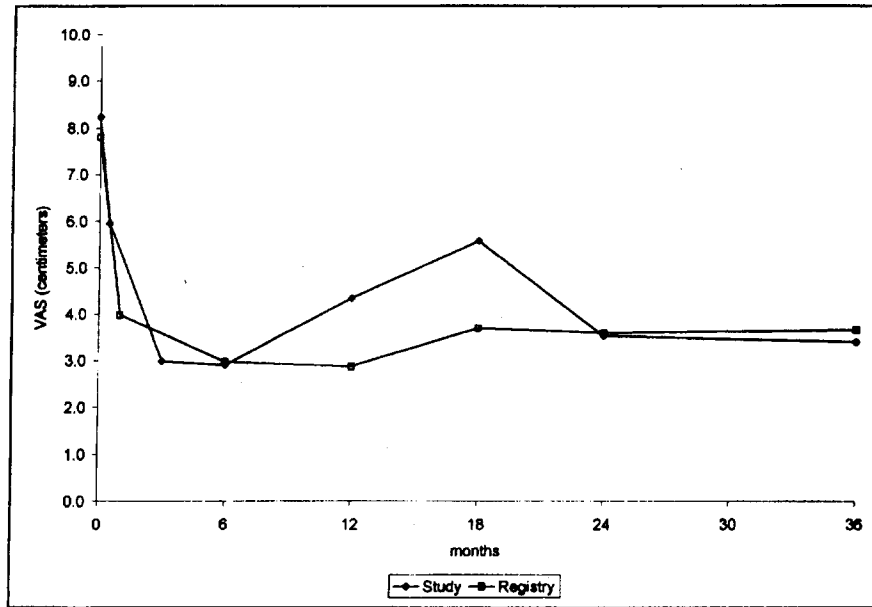
Pain								
Months	0	0.5	3	6	12	18	24	36
Mean	8.2	6.0	3.0	2.9	4.3	5.6	3.5	3.4
n	42	39	29	22	19	8	10	2

Table 6: Mean values, Reduction in Diet, Total Joint

Diet								
Months	0	0.5	3	6	12	18	24	36
Mean	8.6	6.8	3.6	2.7	3.4	4.3	2.9	1
n	42	39	29	22	19	8	10	2

Note: There were 42 pre-op pain and opening measurements from 43 patients. One patient failed to record a pre-op pain or opening measure, however, pain and opening were subsequently reported post-op through 18 months of follow-up for this patient.

Figure 4: Pain Reduction, Total Joint, Clinical Study and Registry Data



Improvement in Interincisal Opening: Total Joint Reconstruction

A patient's interincisal opening was measured in millimeters using either a Therabite™ scale or E-Z flex system. Measurements were taken at the pre-op visit, within 10 days post-op, then at 3, 6, 12, 18, 24, and 36 months after implant. On average, by the 3-month post-op visit there was a significant improvement in opening, Figure 5. These trends are similar to the results presented with the TMJ Registry data, from those patients implanted with a total joint prosthesis, Figure 6. This trend of improvement continued through 36 months post-implant, Table 7.

Figure 5: Improvement in Opening, Total Joint replacement

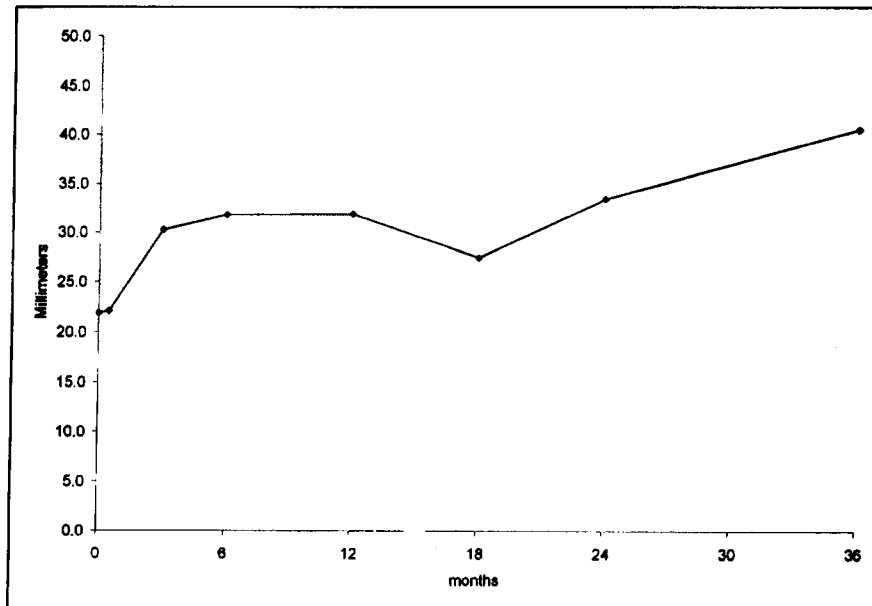
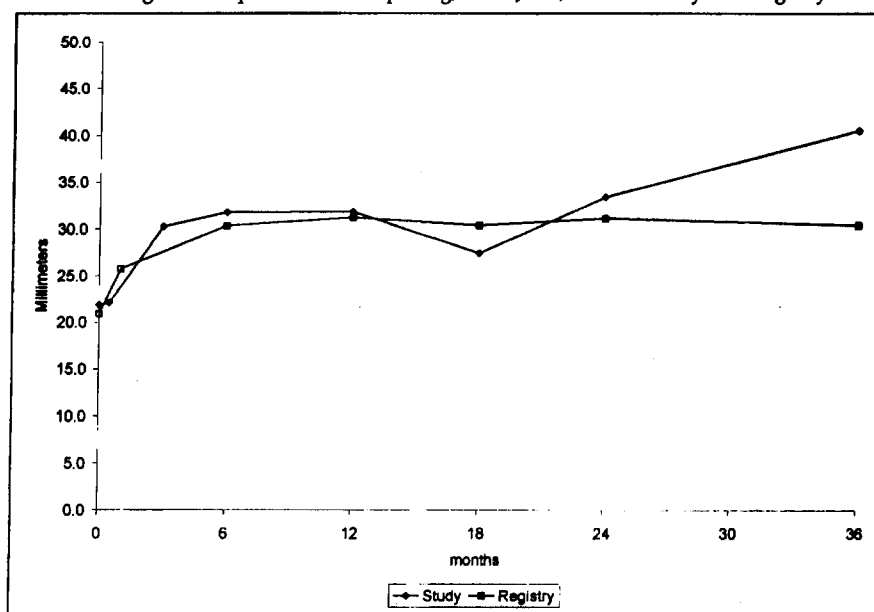


Table 7: Opening Mean values, Total Joint replacement

Opening								
Months	0	0.5	3	6	12	18	24	36
Mean	21.9	22.1	30.3	31.8	31.8	27.4	33.4	40.5
n	37	40	30	22	19	9	12	2

Figure 6: Improvement in Opening, Total Joint, Clinical Study and Registry Data



X. CONCLUSIONS DRAWN FROM THE STUDIES

PRECLINICAL

Pre-clinical tests were undertaken to demonstrate that the TMJ Implants, Inc. prosthetic devices have adequate strength and durability for their intended use. Due to the estimated fatigue limit of 130 lbs, patients with masticatory muscle hyperfunction (clenching or grinding) should not receive this device.

CLINICAL

Safety

A review of the types of adverse events reported within the Prospective Clinical Study TMJ-96-001 demonstrates an incidence rate of all events that is not unexpected of this patient population.

Efficacy

The TMJ Implants, Inc. Registry, though not considered a controlled clinical study, provided significant human experience with the TMJ Metal-On-Metal Total Joint Replacement Prostheses System. The cohorts derived from the Registry data demonstrated reduction in perceived pain and a significant improvement in interincisal opening. The data from the ongoing Prospective Clinical Study, TMJ-96-001, when compared to the cohort and cross-section data from the Registry, demonstrated consistency and reproducibility of pain reduction and improvement in interincisal opening.

PANEL RECOMMENDATION

The Dental Products panel reviewed and considered a prior PMA application submitted by TMJ Implants Inc. for this total joint system with identical indications for use (P990003). The panel recommended approval of this application with the following conditions:

- a prospective study with a control group where possible and 3-5 years of patient follow-up
- clinical study should include measures of pain at one point in time and a record of the pain medications used by patients
- results should be evaluated according to the clinical indications and diagnosis
- different types of prosthetic devices included in this PMA should be evaluated separately
- patient labeling should state that studies do not reveal that pain is significantly modified
- detailed material properties should be provided for all components, and in particular for the patient specific devices and the TMJ Condylar prosthesis with the polymethylmethacrylate (PMMA) head
- fatigue and wear testing should be performed using heavier loads
- wear testing should be validated by comparison of tested specimens with explanted devices
- analysis of wear debris should be performed
- a justification should be provided through both clinical and preclinical data on the continued use of the TMJ Condylar prosthesis with the PMMA head, given that this portion of the device demonstrates increased wear
- a consumer hotline should be developed for patients to call to have questions answered and to resolve complaints

The conditions for approval raised during that panel meeting are relevant to the current submission, therefore additional panel review was not needed.

XI. FDA DECISION

FDA concurred with the panel recommendation and continued to work with TMJ Implants Inc. to provide additional data and bring this application into a final approvable form. TMJ Implants Inc. withdrew the PMMA headed device from consideration, provided additional fatigue and wear testing using heavier loads, and provided additional information on follow-up of patients in the prospective study. The sponsor also agreed to complete a post-approval study that would continue to follow enrolled patients in the prospective study out to three years. TMJ Implants Inc. will also provide analysis of any explanted devices. The additional patient data, fatigue testing plan to examine explanted devices, and post-approval study requirements addressed the remaining FDA and panel concerns. FDA inspections completed January 4, 2001 determined the manufacturing facilities to be in compliance with the Quality System Regulations (QSR).

CDRH issued an approval order on January 5, 2001

CDRH issued a tracking order on January 5, 2001.

XII. APPROVAL SPECIFICATIONS

- Directions for use: See the labeling.
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.
- Postapproval Requirements and restriction: See approval order.